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Patrick J. Fay, Esq. FAY KAPLUN & MARCIN, LLP Suite 702 150 Broadway New York, NY 10038			STIGELL, THEODORE J	
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**BEFORE THE BOARD OF PATENT APPEALS
AND INTERFERENCES**

Application Number: 10/768,571

Filing Date: January 29, 2004

Appellant(s): WEAVER ET AL.

Oleg F. Kaplun
For Appellant

EXAMINER'S ANSWER

This is in response to the appeal brief filed 6/1/2009 appealing from the Office action
mailed 12/8/2008.

(1) Real Party in Interest

A statement identifying by name the real party in interest is contained in the brief.

(2) Related Appeals and Interferences

The examiner is not aware of any related appeals, interferences, or judicial proceedings which will directly affect or be directly affected by or have a bearing on the Board's decision in the pending appeal.

(3) Status of Claims

The statement of the status of claims contained in the brief is correct.

(4) Status of Amendments After Final

The appellant's statement of the status of amendments after final rejection contained in the brief is correct.

(5) Summary of Claimed Subject Matter

The summary of claimed subject matter contained in the brief is correct.

(6) Grounds of Rejection to be Reviewed on Appeal

The appellant's statement of the grounds of rejection to be reviewed on appeal is correct.

(7) Claims Appendix

The copy of the appealed claims contained in the Appendix to the brief is correct.

(8) Evidence Relied Upon

4,447,237	Frisch et al.	5-1984
5,009,391	Steigerwald	4-1991

3,673,612	Merrill et al.	7-1972
2004/0267185	Weaver et al.	12-2004
2005/0049555	Moorehead et al.	03-2005

(9) Grounds of Rejection

The following ground(s) of rejection are applicable to the appealed claims:

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

First Rejection

Claims 1-7, 10, 12-14, 16-17 are rejected under 35 U.S.C. 103(a) as being unpatentable over Frisch et al. (4,447,237) in view of Merrill et al. (3,673,612). Frisch discloses most of the limitations recited in the claims listed above including a pressure

activated valve (see at least Figures 1-5 and 12) comprising a valve housing (2) defining a lumen (3) for receiving bodily fluids therein, a flexible membrane (20) disposed in the valve housing, the flexible membrane including a slit (23) extending therethrough so that the flexible membrane may be moved between an open and a closed configuration based on fluid pressure within the lumen. The examiner contends that the limitation of "the flexible membrane may be moved between an open and closed configuration based on fluid pressure within the lumen" is a functional limitation of which the prior art need only be capable of performing. The examiner contends that there is a fluid pressure at which the valve will open even though the device appears to be designed to resist opening under fluid pressure generated from fluid in the body. Frisch also discloses that the blood contacting surfaces should be coated with a non-thrombogenic coating (see column 12, lines 9-28).

Frisch fails to explicitly disclose that the nonthrombogenic coating includes hydrogel. The examiner first notes that such a limitation is a mere design consideration as the applicant has not disclosed that a hydrogel coating works better than any other coating or solves a problem that other coatings are not capable of solving. It would have been obvious to one having ordinary skill in the art at the time the invention was made to use hydrogel, since it has been held to be within the general skill of a worker in the art to select a known material on the basis of its suitability for the intended use as a matter of obvious design choice. *In re Leshin*, 227 F.2d 197, 125 USPQ 416 (CCPA 1960).

Furthermore, Merrill discloses an anticoagulant coating for medical devices comprising a combination of an anticoagulant and a hydrogel. Merrill teaches that such a coating on medical devices provides many advantages such as a more uniform distribution of heparin and lower costs. It would have been obvious to one of ordinary skill in the art at the time of the invention to modify the device of Frisch with the coating of Merrill to make a more efficient and cheap valve assembly.

Second Rejection

Claims 8-9, 18 and 20-21 are rejected under 35 U.S.C. 103(a) as being unpatentable over Frisch *et al.* (4,447,237) and Merrill et al. (3,673,612) in view of Steigerwald (5,009,391). Frisch and Merrill disclose most of the limitations recited in the independent claim but fail to disclose abutting flexible membranes. Steigerwald teaches abutting two flexible membranes adjacent to one another. (See Fig. 4d.) Thus, it would have been obvious to one of ordinary skill in the art at the time of the invention to modify the disclosure of Frisch and Merrill with the teachings of Steigerwald to provide a valve with abutting flexible membranes.

Third Rejection

Claims 18 and 20-21 are rejected under 35 U.S.C. 103(a) as being unpatentable over Steigerwald (5,009,391) in view Merrill et al. (3,673,612). Steigerwald discloses most of the limitations recited in the claims listed above including a pressure activated valve (see at least Figures 1-10) comprising a valve housing (22) defining a lumen for receiving bodily fluids therein, and a flexible member (76, 82 or 90,94) disposed in the

valve housing, the flexible member comprising a plurality of flexible membranes (76, 82 or 90, 94) stacked on one another, each of the flexible membranes including at least one slit (88a-88c or 92a-92c, 96a-96c) extending therethrough so that each flexible membrane may be moved between an open and a closed configuration based on fluid pressure within the lumen, wherein when all of the flexible membranes are moved to an open position, the flexible member is open to permit fluid flow through the housing. The examiner contends that the limitation of "each of the flexible membranes including at least one slit extending therethrough so that each flexible membrane may be moved between an open and a closed configuration based on fluid pressure within the lumen, wherein when all of the flexible membranes are moved to an open position, the flexible member is open to permit fluid flow through the housing" is a functional limitation of which the prior art need only be capable of performing. The examiner contends that there is a pressure at which the valve will open based on the fluid pressure even though the device is designed to be opened by the insertion of a medical device.

Steigerwald fails to explicitly disclose a nonthrombogenic coating that includes hydrogel.

Merrill discloses an anticoagulant coating for medical devices comprising a combination of an anticoagulant and a hydrogel. Merrill teaches that such a coating on medical devices provides many advantages such as a more uniform distribution of heparin and lower costs. It would have been obvious to one of ordinary skill in the art at the time of the invention to modify the device of Steigerwald with the coating of Merrill to

make a more efficient and cheap valve assembly capable of providing an anticoagulant capability.

Fourth Rejection

Claims 1-10, 12-14, 16-18, 20 and 21 are rejected under 35 U.S.C. 103(a) as being obvious over Weaver et al. (US 2004/0267185) in view of Merrill et al. (3,673,612). Weaver discloses a pressure activated valve comprising a valve housing (18, 20), a flexible membrane (100) disposed in the valve housing, the membrane including a slit (112) extending through the housing so that the membrane may be moved between an open and closed configuration based on fluid pressure delivered by a dialysis machine. Weaver does not teach to include a nonthrombogenic coating made of a hydrogel on the contacting surfaces of the membrane.

Merrill discloses an anticoagulant coating for medical devices comprising a combination of an anticoagulant and a hydrogel. Merrill teaches that such a coating on medical devices provides many advantages such as a more uniform distribution of heparin and lower costs.

It would have been obvious to one of ordinary skill in the art at the time of the invention to modify the device of Weaver et al. with the coating of Merrill to make a more efficient and cheap valve assembly capable of providing an anticoagulant capability.

Fifth Rejection

Claims 1-10,12-14,16-18, 20 and 21 are rejected under 35 U.S.C. 103(a) as being obvious over Moorehead et al. (US 2005/0048555) in view of Merrill et al. (3,673,612). Moorehead discloses a pressure activated valve comprising a valve housing (15), a flexible membrane (24) disposed in the valve housing, the membrane including a slit (26) extending through the housing so that the membrane may be moved between an open and closed configuration based on fluid pressure delivered by a dialysis machine. Moorehead does not teach to include a nonthrombogenic coating made of hydrogel on the contacting surfaces of the membrane.

Merrill discloses an anticoagulant coating for medical devices comprising a combination of an anticoagulant and a hydrogel. Merrill teaches that such a coating on medical devices provides many advantages such as a more uniform distribution of heparin and lower costs.

It would have been obvious to one of ordinary skill in the art at the time of the invention to modify the device of Moorehead with the coating of Merrill to make a more efficient and cheap valve assembly capable of providing an anticoagulant capability.

(10) Response to Argument

Frisch et al. (4,447,237) in view of Merrill et al. (3,673,612) (First Rejection)

In response to the applicant's argument that Frisch does not disclose "a flexible membrane disposed in the valve housing, the flexible membrane including a slit extending therethrough so that the flexible membrane may be moved between an open and a closed configuration based on fluid pressure within the lumen", the examiner

respectfully disagrees. In regard to claims 1, the examiner first points out the use of the phrase "may be moved". It is the examiner's position that this phrase provides for the possibility that the claimed membrane does not have to open and close based on a fluid pressure. This situation is analogous to a weatherman saying that "it may rain today". It does not mean that there is a 100% certainty of rain and that rain is a definite outcome. Similarly, the applicant has only claimed a membrane that "may" open and close based on fluid pressure in the lumen. Since the device of Frisch is specifically designed to resist opening when used in the disclosed applications, the examiner contends that there are certainly disclosed situations where the valve will not open and close based on fluid pressure in the lumen. These situations are covered by the scope of the applicant's claims.

Furthermore, in regard to claims 1, 10, and 14, the examiner maintains that the limitation discussed above is a functional limitation of which the prior art only has to be capable of meeting. It is the examiner's position that even though the device of Frisch is not designed to be opened and closed by the fluid pressure encountered in the disclosed applications (ex. induced hypothermia and hemodialysis), there are still fluid pressures that would open the valve in the presence of such a pressure and close the valve in the absence of such a pressure. Such pressures would not necessarily destroy the device as the device is made of elastomeric material and therefore is resilient.

In response to the applicant's argument that it would not have been obvious to have modified the coating of Frisch with a hydrogel component, the examiner respectfully disagrees. The applicant argues that hydrogel is not a known biologically

active anticoagulant and therefore it would not have been obvious to modify the coating of Frisch with a hydrogel. The examiner agrees that hydrogel by itself is not a known anticoagulant but Merrill does not teach a hydrogel by itself. Instead, Merrill teaches a material that includes anticoagulant and a hydrogel and teaches that the material provides distinct advantages for blood dialysis applications. See at least column 4, lines 24-40. Therefore, Merrill does in fact show that non-thrombogenic coatings comprising hydrogel are in fact known as being useful in the blood dialysis art. The applicant further argues that Merrill does not teach a valve or a coating including hydrogel but instead teaches a material that may be used in medical devices. The examiner respectfully disagrees. Merrill specifically teaches that the disclosed composition can be formed into a wide variety of shapes and elements including at least membranes and valves (see at least column 4, line 29-33) and is useful for elements that are in direct contact with human blood (see column 4, lines 73-74). One of ordinary skill in the art would recognize that the material disclosed by Merrill would be useful as a coating or a membrane for a medical device that is used in dialysis applications. Since Frisch discloses a device that is to be used in dialysis applications, the examiner maintains that the combination is proper and that it would be obvious to substitute the coating of Frisch with the material of Merrill.

Frisch et al. (4,447,237) and Merrill et al. (3,673,612) in view of Steigerwald (5,009,391) (Second Rejection)

In response to the applicant's argument that Steigerwald does not cure the deficiencies of Frisch and Merrill, the examiner respectfully disagrees. The applicant

simply argues that Steigerwald does not teach a valve that is disclosed as being open by fluid pressure. The examiner is not relying on Steigerwald for a teaching of a valve that opens based on fluid pressure and furthermore the examiner maintains that the valve of Steigerwald is capable of opening at some fluid pressure.

Steigerwald (5,009,391) in view Merrill et al. (3,673,612) (Third Rejection)

In response to the applicant's argument that Merrill does not cure the deficiencies of Steigerwald, the examiner respectfully disagrees. The applicant simply argues that Steigerwald does not teach a valve that is disclosed as being open by fluid pressure and that Merrill does not cure this deficiency. However, the examiner is not relying upon Merrill for a teaching of a valve that opens based on fluid pressure and furthermore the examiner maintains that the valve of Steigerwald is capable of opening at some fluid pressure.

Weaver et al. (US 2004/0267185) in view of Merrill et al. (3,673,612) (Fourth Rejection)

The applicant has successfully disqualified the Weaver '185 reference under 35 U.S.C. § 103(c) since the Weaver '185 reference and the instant application were commonly owned at the time of the invention. At the time of the invention, Weaver '185 and the instant application were commonly owned by Scimed Life Systems, Inc.. The examiner notes that Weaver '185 only qualified as a 102(e) reference.

Moorehead et al. (US 2005/0048555) in view of Merrill et al. (3,673,612) (Fifth Ground of Rejection)

The applicant has successfully disqualified the Moorehead '555 reference under 35 U.S.C. § 103(c) since the Moorehead '555 reference and the instant application were commonly owned at the time of the invention. At the time of the invention, Moorehead '555 and the instant application were commonly owned by Scimed Life Systems, Inc.. The examiner notes that Moorehead '555 only qualified as a 102(e) reference.

(11) Related Proceeding(s) Appendix

No decision rendered by a court or the Board is identified by the examiner in the Related Appeals and Interferences section of this examiner's answer.

For the above reasons, it is believed that the rejections should be sustained.

Respectfully submitted,

/Theodore J Stigell/

Examiner, Art Unit 3763

Conferees:

/Nicholas D Lucchesi/

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